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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,637	10/27/2005	Min-Hyo Seo	1599-0293PUS1	9196

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BIRCH STEWART KOLASCH & BIRCH
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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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11/06/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/554,637	Applicant(s) SEO ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/24/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendments to the claims filed 07/17/2009 have been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4 ,7-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al (WO 03/033593) in view of Li et al. (Polymer, 39, pp. 4421-4427 (1998)), for the reasons set forth in the previous office action filed 07/17/2009.

Response to Arguments

Applicant's arguments filed 07/17/2009 have been fully considered but they are not persuasive. Applicants assert that the PLA derivatives of Seo are linear and limited to a molecular weight less than 2,000 Daltons therefore by applicants reasoning they would fail to entrap drugs in the micelle for extended periods of time.

The relevance of these assertions is unclear. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the micelle does not entrap drugs for a long time) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore it was noted by the examiner that Seo does not describe multiarm block copolymers which is why the reference was combined with Li. If Seo did teach multiarm block copolymers with the same-end terminated polymers disclosed within it would be a 35

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U.S.C. 102 type of rejection on its own merit. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Clearly as noted in the past office action one of ordinary skill in the art would have been motivated to produce multi-arm copolymers of the PLGA carboxyl terminated PLGA polymers of Seo since multiarm copolymers as taught by Li were well known to have advantageous properties for drug delivery compared to their linear counterparts.

Applicants further argue that the Li star block copolymers are clearly distinguished from the claimed invention in its chemical structure in that Li uses PLA bound to large PEG multiarm polymers while their claimed invention only uses a small molecule core. Applicants further contend that Li's polymer forms a hydrogel upon addition of water and does not form micelles as claimed.

The relevance of these assertions is unclear. The examiner considers PEG as meeting ethylene glycol since PEG is comprised of units of ethylene glycol. Furthermore the PEG units drawn in figure 1 and the table 1 are much smaller in overall weight than PLA and PGA for the entire polymer (around 14-33 wt % PEG while PLA and PGA comprised the rest of the copolymers) therefore the examiner assumes that the overall characteristic of the polymer will be similar a PLA multiarm polymer with a small core molecule. Regardless since applicants claims do not preclude a polymer of PEG from being present in the claimed formula the examiner assumes that any multi-arm

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copolymer within applicants claimed polymer will have the same properties including its micelle forming properties. It is further noted by the examiner that the ability to form a micelle or a polymers critical micelle concentration (CMC) is a product of its structure and the amount and type of solvent used, therefore the same polymer will have the same micelle forming characteristics.

Claims 1-5 and 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al (WO 03/033593) in view of Li et al. (Polymer, 39, pp. 4421-4427 (1998)) in view of Sodergard (US 2004/0091573), this new rejection was necessitated by applicants amendments to the claims.

Seo and Li are disclosed in the previous office action filed 07/17/2009. The reason to combine the two references as disclosed previously would be to produce multi-arm copolymers of the PLGA carboxyl terminated PLGA polymers of Seo with the advantageous properties of multi-arm block copolymers for drug delivery compared to their linear counterparts including enhanced structural stability and a slower biodegradation rate. The two references however by combination do not disclose the specific polyol cores claimed in dependent claims 5 and 9.

Sodergard discloses multiarm polymers containing a core molecule including maltitol along with numerous other naturally occurring polyfunctional compounds of sugars and tri-saccharides and polymer arms containing units derived from lactic and glycolic acid. See [0006]-[0016]. Thus sodergard is used primarily for the disclosure within that applicants claimed saccharide cores were well known at the time of the invention to be used as polyol cores in PLA multi-arm polymers. Since Sodergard

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discloses the use of PLA in the described multi-arm polymers one of ordinary skill in the art would have a high expectation of success in adding the PLA polymers of Seo to the star polymer of Sodergard. The reason to make such a modification is provided by Li who disclosed that multiarm polymers were well known to have advantageous properties for drug delivery compared to their linear counterparts. Since Seo relates to PLA polymers for solubilizing poorly soluble drugs it would have been obvious for one of ordinary skill in the art to make a multiarm PLA polymer in order to make a drug delivery micelle composition that shows enhanced structural stability and has a slower biodegradation rate.

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618